

REMARKS

With entry of this amendment, Claims 19-38 are pending. No new matter has been added.

35 U.S.C. §103(a)

Claims 19-38 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jain *et al.* (EP 812,587). The Office Action states that Jain *et al.* teaches a non-staining composition of nimesulide, which contains monoglycerides, such as glycerol monooleate, in an amount ranging from 0.5% to 12% by weight and that it is well known in the art that nimesulide possesses both anti-inflammatory and analgesic properties. Applicants traverse this rejection.

The compositions described by the present invention are anhydrous in nature. Jain *et al.* requires water and surfactants to form emulsions that have the correct hydrophilic and lipophilic balance. Because hydrophobic components that are mixed with water are not miscible, surfactants are utilized to reduce the surface tensions and to create stable dispersions. As the Examiner points out, on page 5, line 2, Jain states that “water in varying concentration may be added to provide requisite hydrophilic nature to the composition.” While this sentence states that water *may* be added, it also adds that the hydrophilic nature of the composition is required. Additionally, all of the examples in Jain *et al.* contain water and the summary of the invention requires the use of water. “[W]ater is required for the composition in the range of 1% to 15% w/w, preferably 9% to 11% w/w and more preferably in the range of 9.5% to 10.5% w/w.” (page 3, lines 35-36). A prior art reference must be considered in its entirety, *i.e.* as a whole, including portions that would lead away from the claimed invention. MPEP 2141.03 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (1984). Therefore, while Jain *et al.* states the water is both required and optional, it only teaches a method of making a composition that requires water and states that the composition must be hydrophilic. Taken as a whole, it teaches that water is required. It is therefore not enabling for an anhydrous composition as currently claimed.

The Office Action further states “it would have been obvious to one having ordinary skill in the art to optimize the range of the glyceryl monoolein in order to improve the surfactant properties of the sparingly soluble nimesulide.” However, there is no suggestion or teaching in Jain *et al.* that they are not using the optimum range of their surfactant. The surfactant in the compositions of Jain *et al.* ranges from 0.5 to 12% w/w. The concentration of the glyceryl monoolein-solvent phase claimed in the present application is 17% to 59%. There is no teaching or suggestion by Jain *et al.* to try any other range, let alone a range that is nearly double the range taught. Furthermore, as shown in the attached Declaration of Dr. Embil, the concentrations and the specific formulas used to make the claimed compositions offer a significant improvement in the *in vitro* release of nimesulide over the compositions taught in Examples 2 and 4 of Jain *et al.*

The claims of the present invention use the phrase “consisting essentially of”. This limits the scope of the claim to the specified materials or steps “ and those that do not materially affect the basic and novel characteristics” of the claimed invention. MPEP 2111.03 citing *In re Herz*, 537 F.2d 549, 551-52, 190 U.S.P.Q. 461, 463 (CCPA 1976). The addition of water and a reduced concentration of surfactant, as required and taught by Jain *et al.*, would materially affect the basic and novel characteristics of the claimed anhydrous invention. Applicants respectfully assert that Jain *et al.* does not teach, suggest or disclose the present invention as currently claimed. Applicants respectfully request the Examiner withdraw this rejection.

35 U.S.C. §103(a)

Claims 19-25 and 30-38 are rejected under 35 U.S.C. §103(a) over Kruse *et al.* (U.S. Patent No. 5,744,458). The Office Action states that Kruse *et al.* teaches a topical composition which contains nimesulide and glyceryl mono-fatty acid esters. Applicants traverse this rejection.

Kruse *et al.* teaches a lotion containing an effective concentration of one or more of the compounds with an emollient, and “the balance water, a suitable buffer, a C₂ or C₃ alcohol, or a mixture of water of the buffer and the alcohol.” (Kruse *et al.*, column 114,

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lines 35-45). As argued above, the present invention is essentially anhydrous in nature. The addition of water as required in Kruse would materially alter the present invention as currently claimed. Kruse *et al.* does not teach, or disclose the making of an anhydrous composition. Applicants request this rejection be withdrawn.

Applicants respectfully submit that this is a complete response to the Office Action dated September 24, 2003 and that Claims 19-38 are patentable. Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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